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Cardiac pacemaker

The Invention relates to a cardiac pacemaker in accordance with the preamble of the main claim.

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A generally known cardiac pacemaker is the so-called QT-or stimulus-T pacemaker such as is described for example in US 422 8 803. Such a pacemaker has means with which the median stimulation frequency can be adapted to changes in physical and psychic stress.

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To this end a circuit is provided which evaluates the ECG signal derived intracardially, detecting the beginning or the maximum of the T wave. Since the time interval between stimulation and the start of the T wave, the so-called stim-T interval shortens with increasing stress, the circuit delivers a physiological measuring parameter with which the stimulation frequency can be adapted to changing stresses.

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The principle disadvantage of a frequency control system of this kind is given in that the stim-T interval does not shorten only with an increase in stress but to a considerably greater degree through the rise of the stimulation frequency itself. Frequency control of this type correspondingly requires special measures in order to avoid positive feedback.

A further disadvantage of this system of frequency control is the fact that the measured stim-T intervals are determined from humours i.e. react on the basis of the hormones poured out via the adrenal cortex and transported via the blood circulation.

In principle, in the regulation of the stimulation frequency in cardiac pacemakers it is an essential goal to adapt the stimulation frequency not only to rising physical stresses, but in so doing also to take into account the individual myocardial capacity of the patient. This means that the stimulation frequency is only increased with rising stress as long as thereby a rise in the heart time volume (HTV) is achieved. This is intended to prevent the myocardium from being overloaded and damaged by too high a stimulation frequency ("overpacing")

An attempt has been made to achieve this control by measuring the beat volume BV or an HTV-dependent measuring parameter, such as for example the central venous oxygenation (sO₂)

From WO 89/06990 is known a method for haemodynamic optimisation of the stimulation frequency, which uses the measurement of the central venous oxygenation sO₂, dependent on the heart time volume, in combination with a modulation of the stimulation frequency ΔHR over phases of two to four minutes. Optimisation of

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of the individual pulse modulation, has in practice still proved too inaccurate to be able to carry out reliable haemodynamic optimisation. This means that optimisation of the stimulation by controlling the heart time volume presents itself in practice as problematic, since either the specific sensor catheters for measuring the beat volume or the HTV-dependent measuring parameters still have no adequate long-term stability, or measurements of the beat volume using standard catheters via the impedance are not sufficiently reliable. Moreover the evaluation becomes very complex since the mechanical transmission functions also detected and which falsify the measuring result must also be taken into account.

The object underlying the invention is to create a cardiac pacemaker which renders possible quick and accurate regulation of the stimulation frequency or respectively of the duration of the stimulation interval, and overloading by too high a stimulation frequency is avoided.

This object is accomplished according to the invention by the features of the main claim.

The cardiac pacemaker according to the invention which has an individually optimised regulation of the duration of the stimulation interval, avoids the necessity of determining a BV- or HTV-dependent measuring parameter and makes possible, through evaluation of the electric restitution or of the gradient of the electric restitution with the aid of the standard detection of the endocardiac FOG, a regulation of the stimulation frequency or of the duration of the stimulation interval by means of a function parameter of the heart, which directly reproduces the stress state of the patient, changes in the capacity of the myocardium and acute worsening of

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As the evaluation variable of the electric restitution, advantageously a dimensionless variable e.g. the gradient (ERG) or the relative change in the electric restitution can be used in order to achieve load-dependent control. This is possible since this gradient coincides with the rise in the physical load, whilst it rises with increasing stimulation frequency. Moreover it was also found that the change reaction is based mainly on a change in the time constants of the exponential restitution function and this time

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Fig.3 characteristic curves of the gradient of the electric restitution independence on

the stimulation frequency on occurrence of an ischemia and

Fig. 4 a block diagram of an embodiment of the cardiac pacemaker according to the present invention.

The dependence of the duration of the action potential AP of the myocardium as a function parameter of the duration of the diastole t_d is designated as electric restitution. If this is spontaneously changed during a single heart cycle, for example through an extrasystole, then the action potential or its duration changes. The duration of the action potential is defined by the interval between the beginning of the stimulation and the time at which the action potential has sunk by 90%, and it decreases if the time interval between two successive stimulation pulses becomes smaller. Here a distinction is to be made between the APD change after an extrasystolic stimulation interval and the APD change after a change in the median or basic heart frequency ($HR = 1 \text{ BCL}$) according to prior art. This alteration behaviour after an extrasystolic stimulation interval can be described by a double exponential function which is referred to as the electric restitution curve ER.

The electric restitution curve (ERC) is thus defined as a function of the action potential duration APD of the cycle length of a previous extrasystolic stimulation pulse interval ESI, i.e. of an individual stimulation pulse interval which is changed from the basic cycle length (BCL), i.e. the median stimulation interval duration by $\pm \Delta \text{ESI}$, and which corresponds to the diastole.

The function can be described as

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Herein, APD_{Pl} is the plateau value, $A1$ and $T1$ are the amplitude and time constant of the quick phase of the restitution and $A2$ and $T2$ are the amplitude and time constant of the slow phase of the restitution.

As a measuring parameter to determine the electric restitution curve, as indicated above, in principle the action potential duration APD is determined which can be measured by special electrodes. Tests have shown however that in measuring the ECG also the so-called QT interval, i.e. the duration of the interval between the Q peak and the end of the T wave of the intracardial ECG has the same restitution characteristic as the APD. On stimulating the ventricle with a cardiac pacemaker it is more expedient to measure, instead of the QT interval as the measuring interval, the stim-T interval STI, i.e. the interval between stimulation pulse and T wave.

In Fig. 1 is represented as the electrical restitution 30 curve (continuous line) the course of the action potential duration APD in dependence on the length of individual extrasystolic intervals of a normal healthy myocardium for the rest phase and for a load phase. Here in both phases respectively the optimum adapted

stimulation frequency HRO or the optimum basic cycle length $BCLo = 1/HRO$ (i.e. the median duration of the stimulation interval) was changed in individual extrasystolic stimulation intervals ESI and then the corresponding change in the action potential duration APD measured. The restitution curves thus produced correspond to the exponential functions described by the above equation. The optimum basic cycle length $BCLo$ for rest (90 ins) and for a load (500 ins) are represented by the broken arrows, i.e. the respective basic cycle length or median interval duration was altered by $\pm\Delta ESI$ to form extrasystolic intervals, and respectively as the reaction the action potential duration or the QT - or $stim-T$ interval was measured as the measuring parameter. Here mean durations of the stimulation interval were alternately so shortened and prolonged by positive and negative ΔESI values that the adjusted median interval duration remains the same. Preferably the $\pm\Delta ESI$ remains the same during a change, i.e. the interval duration is shortened and prolonged by the same value. The change can be repeated periodically at an interval of a plurality pulses, however it can also be carried out continuously, i.e. each stimulation pulse is alternately shortened or prolonged. The broken lines in Fig. 1 represent the curves of the QT or $stim-T$ intervals of an ECG with continuous alteration of the basic cycle length, or respectively with continuous modulation, which is used for example in a QT pacemaker according to prior art. As can be recognised, these characteristic curves are clearly different from the electric restitution curves with a differing load, and with increasing load, in addition to a reduction of the plateau value of the respective curve with a corresponding displacement to the left also a steeper rise in the curve was measured.

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Fig. 2 shows that the exponential rise of the gradient of the electric restitution ERG as a function of a rising stimulation frequency HR with rising load is displaced to the right. It can be recognised that in the respective optimum heart frequency, the associated ERG_0 values, which correspond to the plateau values APD_{p1} in Fig. 1, have approximately the same level, however the values can also be different. These values can be selected in a frequency control system as set

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modulator 9 to fix and modulate the stimulation interval and which is connected to the stimulation pulse generator 10. Furthermore a calculation stage 4 is provided which receives a signal from the detection stage 3 and from the modulator 9, and a stage 5 to form the median value, a set value memory 6 and a set/actual value comparator 13.

The functioning of the cardiac pacemaker is as follows. 5 The stimulation pulse generator 10 supplies a stimulation pulse to the stimulation electrode and the ECG amplifier amplifies the intracardial ECG signal derived via the stimulation electrode 1. From this amplified signal, the detection stage 3 analyses the interval duration STI between the stimulation pulse and the T wave which corresponds to the QT interval or the action potential duration. In the calculation stage 4, the gradient of the electric restitution ERG is calculated, however others of the above-mentioned variables can also be used. To this end first of all, triggered by the modulator 9, the change $\pm \Delta \text{STI}$ is calculated, with the stim-T interval value supplied by the detection stage, which change has been caused by the change ΔESI in the stimulation interval, and then the quotient $\text{ERG} = \Delta \text{STI} / \Delta \text{ESI}$ is determined. In the median value stage 5, the median value ERG_m of the ERG values is calculated over a plurality of change cycles. With the arrow from the exit of the median value stage 5 to the set value memory 6 is indicated that the ERG_m value, which in the body's rest state is measured at a median stimulation frequency of roughly 90/min, is stored as the set value.

In the set value/actual Value comparator 13, the difference between the median value of the gradient of the electric restitution ERG_m and the set value ERGs is formed, and is given as the difference value ΔERG

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to the control stage 8, the latter being used to adjust the median stimulation frequency HRp. This is calculated for example with the aid of the following functions:

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$$HR_o = HR_{min} + k \cdot \Delta ERG,$$

wherein HR is so regulated that HR is < HRmax. Here HRmin and HRmax are minimum or maximum frequencies which can be predetermined by external programming and stored in the memory 7, and k is a proportionality factor. HRmin is generally predetermined by the optimum median stimulation frequency HRo in the rest state. The basic frequency HRo thus determined is supplied to the modulation stage 9, in which the basic cycle length BOL = 1/HRo is modulated periodically with an interval change $\pm \Delta ESI$ and the resulting stimulation interval ESI = BCLo + ΔESI is formed. In the following stimulation pulse generator 10, the stimulation pulse is then output in dependence on the ESI value. The regulation is repeated until the value ΔERG is zero.

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In the above-described value, as the set value for the gradient of the electric restitution ERGs, the level was selected which arises for the individual load curves according to Fig. 2 at the optimum stimulation frequency HRo, control fluctuations between the values ERG1 and ERG2 being admitted. The set value ERGs can however also be automatically adapted to longer-term fluctuations of the restitution gradient with the aid of a second measuring parameter, independent of the modulation, with which parameter it is possible to recognise the rest state of the patient. In the rest phase then the minimum stimulation rate HRmin is automatically adjusted and the set value ERGs is adapted to the restitution gradient measured at rest. In this manner, the set value is "recalibrated". The

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